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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,392	04/18/2001	Steven M. Ruben	PT020P1	5189

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[REDACTED] EXAMINER

MARTINELL, JAMES

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

DATE MAILED: 06/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/836,392	RUBEN ET AL.
	Examiner James Martinell	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 11,13,17,19 and 22-42 is/are pending in the application.

4a) Of the above claim(s) 11,13,17,19 and 22 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23-42 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

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Applicant's election with traverse of the requirement for restriction in Paper No. 9 is acknowledged. The traversal is on the ground(s) that a search for a given sequence among the Groups outlined in the requirement for restriction would provide useful information. This is not found persuasive because the searches do not overlap sufficiently to obviate the need for additional searching and thus a serious search burden results for the PTO.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11, 13, 17, 19, and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

The disclosure is objected to because it contains an embedded hyperlink and/or other forms of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Hyperlinks and/or other forms of browser-executable code are found in at least the following locations:

- (a) page 5, lines 1-2 and
- (b) page 48, line 28.

The attempt to incorporate subject matter into this application by reference to materials that are not printed publications, but identified only as Accession Numbers (see the instant application, paragraph 786, page 225 and Table 2, pages 225-232), is improper because the materials referred to are subject to change. In addition, the source of the Accession Numbers is not given. For example, in Table 2, the entry for Gene No. 7 refers to Accession No. AA280061. The enclosed copy of the record for Accession No. AA280061 for GenBank® accessed via the NCBI website (which is presumed here to be the database that corresponds to the recited Accession No.) reveals that the entry was created May 17, 1997 and was updated on August 15, 1997. Since such records may be updated and changed, it is not certain just what has been incorporated by reference. In addition, the attempt at incorporation by reference which states, "All references available through the accession numbers are hereby incorporated by reference in their entirety." (paragraph 786, last sentence) is improper because there is no provision for an

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incorporation by reference by reference (*i.e.* a second-hand incorporation by reference) nor is there an adequate definition of the meaning of "references available through." This phrase, loosely interpreted, could be construed such that virtually all of the world's literature could be "available" through these accession numbers if more than one "jump" of references can be made. See MPEP 608.01(p) I. A.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 27, and 29-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, misdescriptive, and inaccurate.

- (a) The recitation of "heterologous polynucleotide" (claims 26, 27, and 36) is vague, indefinite, and incomplete because it is not clear to what the polynucleotide is heterologous.
- (b) The recitation of heterologous polypeptide" (claims 27 and 37) is vague, indefinite, and incomplete because it is not clear to what the polypeptide is heterologous.
- (c) The recitation of "heterologous regulatory sequence" (claims 29, 31, 39, and 41) is vague, indefinite, and incomplete because it is not clear to what the regulatory sequence is heterologous.
- (d) The recitation of "recombinant host cell" (claims 30-32 and 40-42) is vague, indefinite, misdescriptive, and inaccurate because the term is not defined nor is there a recognized class of such host cells. The term "recombinant" is generally applied to nucleic acids or polypeptides and not to host cells.
- (e) The recitation of "full-length polypeptide . . . plasmid HDPSB68 in ATCC Deposit No. PTA840" is vague and indefinite because the instant application does not define what the full-length polypeptide is.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the claimed nucleic acids (*i.e.* sequences that encode SEQ ID NO: 21 (*e.g.*, SEQ ID NO: 8) or portions of SEQ ID NO: 21) or the polypeptides encoded by those nucleic acids. The instant application discusses Gene No. 7 at pages 23-25. Paragraph 8 (page 3) of the instant application states: "Although structurally related, such proteins may possess diverse and multifaceted functions in a variety of cell and tissue types." Thus, without a disclosure of a specific activity or function for the polypeptides encoded by the polynucleotides mentioned in the instant claims, that the instant application does not disclose a patentable utility for the claimed invention because, as is recognized and disclosed in the application, structural relatedness (actually, in this case, sequence relationship, since no secondary or tertiary structural data are disclosed or referred to) and function are not necessarily correlated. In addition, the listing on pages 23-25 (paragraphs 80-83) of numerous putative utilities and the further long, long listing of conjectured utilities on pages 125-225 do not add to the disclosure in a way that is sufficient to satisfy the requirements under 35 USC § 101 in connection with utility for the following reasons.

- (a) No information is offered regarding the diagnosis of any particular disease based upon any particular diagnostic assay.
- (b) A report of a desired result cannot substitute for a disclosure of a patentable utility and a teaching of how to make and use the invention. The instant application merely invites experiment and evokes the hope that the results from a successful experiment will have meaning sufficient to impart a patentable utility to the claimed subject matter.
- (c) It is simply not believable by one of skill in the art that the claimed invention can be used for all of the utilities listed on pages 125-225 of the instant application. Thus, without a

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disclosure of which of the utilities noted on pages 125-225, there is no real disclosure of a patentable utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the previous rejection is incorporated here.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
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